

ABSTRACT

Test devices, systems, and test kits are provided for rapid detection with high specificity of the pathogenic form of prion protein responsible for neurodegenerative diseases affecting humans and animals, such as transmissible spongiform encephalopathy in bovine, sheep, and 5 cats. The present invention is also useful for testing animal feedstock made from animal parts. Results are available in from about 0.5 to about 20 minutes and preferably from about 5 to about 10 minutes after the sample is introduced to the device and system. The devices, systems, and test kits employ proteinase-K to remove noninfectious prion protein from a biological sample, so that the sample may be analyzed by immunochromatography to determine the presence and 10 concentration of pathogenic prion protein. Because the proteinase-K is immobilized on a solid support for *in-situ* removal of interfering components, the present invention obviates the need for subsequent extraction of the desired analyte. All aspects of the present invention are suitable for quantifying the minimal detectable amount of pathogenic prion protein in a biological sample. Moreover, the simplicity of sample preparation makes the present invention suitable for use in 15 the field.

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